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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/612,784
Filing Date: July 02, 2003
Appellant(s): WASIELEWSKI, RAY C.

Ryan Willis
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/14/08 appealing from the Office action mailed 12/17/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The amendment after final rejection filed on 4/24/08 has been entered.

The amendment after final rejection filed on 2/19/08 has not been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Rejection 1, claims 1, 2, 4-6, 14, 15, 27-32, 37-39, and 109 are rejected under 35 U.S.C. 112, second paragraph, has been withdrawn.

Rejection 3, claims 1, 2, 4-6, 14, 15, 27-32, 37, 109 are rejected under 35 U.S.C. 102(b) as anticipated by Kuber has been withdrawn.

(7) Claims Appendix

A substantially correct copy of the appealed claims appears on pages 25-38 of the Appendix to the appellant's brief. The minor errors are as follows: Claims 38 and 39 are withdrawn.

(8) Evidence Relied Upon

DE 19716051 A1	Kuber	11-1997
5,549,701	Mikhail	8-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 4-6, 14, 15, 27-32, 37, 109, and 110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1, "*wherein the augment is formulated not to transform into scar tissue*" is new matter. Further, the paragraph before claims, "*wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue*". The specification does not support a material that does not transform into scar tissue but contains an agent to promote scar tissue.

Regarding claims 27 and 29, "*wherein the augment is formulated not to transform into scar tissue*" is new matter.

Claims 1, 2, 4-6, 14, 15, 27-32, 37 are rejected under 35 U.S.C. 103(a) as obvious over Kuber (DE 19716051, applicant submitted).

1. A prosthetic device for use with a hip replacement prosthesis that includes an acetabular cup assembly to be fastened to a patient's pelvis and a femoral stem to be fastened to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, the prosthetic device comprising:

an acetabular liner B for releasably an acetabular cup permanently mounted to the patient's pelvis (Note that the claim no longer positively claims the mating features and is interpreted as functional language only, however, note figure 4, any of the tab-like elements or figure 3, the indent elements); and

a semiannular augment A to be mounted approximate to a rim of an acetabular assembly liner of a hip replacement prosthesis, wherein the semiannular augment assists in improving stability of a ball joint type coupling by increasing the height of a portion of the rim of the acetabular liner, at least temporarily, between the acetabular assembly liner and a femoral stem of the hip replacement prosthesis while allowing rotational and angular movement between the acetabular cup assembly and the femoral stem;

the semiannular augment being formed from an augment material comprising at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials; and

wherein the augment material is formula not to transform into scar tissue (note Kuber and applicant teach PLLA, see at least applicant's claim 5 [teaching the same material]).

Regarding at least claim 1, however, Kuber fails to teach the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent. It would have been obvious to one having ordinary skill in the art to have utilized any of the known biologic materials (bioresorbable or non-bioresorbable) or combinations thereof and to include an agent to promote scar tissue, clotting, and antibacterial agent for their known biocompatibility and characteristic such as preventing a bacterial infection. Kuber teaches the semiannular augment being formed of PLLA. It is well know in the art to form femoral head retaining structures from other materials including non-resorbable material. It would have been obvious to one having ordinary skill in the art to have made/tried the augment of Kuber comprising any known material in the prosthetic art having predictable results.

In the alternative, if Kuber does not teach a liner/cup configuration, under 35 U.S.C. 103(a): Regarding the mating features to releasable engage corresponding mating features of an acetabular cup, these features are well known in the art; see Mikhail (5,549,701) teaching a liner 12 having mating features 34 and 30. Note Mikhail teaches the liner can be implanted into an acetabular cup 14 as shown in figure 1 or directly implanted into the acetabulum as shown in figure 2. It would have been obvious to one having ordinary skill in the art to have used any mating features **and a cup** known in the art such as

those taught by Mikhail on/with the plastic liner B of Kuber to anchor the liner in a cup preventing relative motion which produces wear debris.

Regarding claims 2 and 29, see fastener C made of PLLA.

Regarding claims 4 and 30, fastener C is a screw.

Claims 6 and 32 only further defines the ECMs.

Regarding at least claim 14, the screw is integrated.

Regarding at least claim 15, applicant's specification teaches various fastening means including screws; see paragraph 0032 and 4. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to snap-on retention members. Applicant has not disclosed that said configuration provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either screws or a snap-on configuration. Therefore, it would have been obvious to one of ordinary skill in the art to modify Kuber to obtain the invention as claimed with expected results.

Regarding claim 37, see reasoning above.

(10) Response to Argument

Rejection 1: Claims 1, 2, 4-6, 14, 15, 27-32, 37 are rejected under 35 U.S.C. 112, second paragraph, has been withdrawn.

Rejection 2: Claims 1, 2, 4-6, 14, 15, 27-32, 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicant cites paragraph [0040] of the specification stating:

[0040] In the exemplary embodiment utilizing the biologically reabsorbable snap-on augments 26, such augments 26 could be formulated to absorbed over a relatively short period (i.e., several weeks or months) and ***could also be formulated so as to be replaced by tissue (such as scar-tissue)*** that would provide for long-term hip stability and, hopefully, normal motion. Such formulations of biologic materials are well known by those of ordinary skill in the art.

It is the Examiner's position that **"could also be formulated so as to be replaced by tissue (such as scar-tissue)**" does not inherently conclude the claimed exact opposite "*wherein the augment material is formulated **not to** transform into scar tissue".* One skilled in the art would not read the list of augment materials disclosed in the originally filed application and conclude the augments are "formulated not to transform into scar tissue". The Examiner concludes the opposite, as stated in paragraph [0040] of the specification.

The combination of claim limitations, "*wherein the augment is formulated not to transform into scar tissue*" and "*wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue*", is simply unsupported.

Additionally, the specification teaches "formulated to be replaced by" and not "transform" as claimed which is different in scope.

Rejection 3*:* Claims 1, 2, 4-6, 14, 15, 27-32, 37, 109 are rejected under 35 U.S.C. 102(b) as anticipated by Kuber has been withdrawn.

Rejection 4: Claims 1, 2, 4-6, 14, 15, 27-32, 37 are rejected under 35 U.S.C. 103(a) as obvious over Kuber.

Applicant states on page 20, “Group 1: Claims 1, 2, 4-6, 14 and 15" which has been interpreted as the listed claims stand or fall together.

Applicant argues that the augment of Kuber is not formulated to not transform into scar tissue as require by claim 1. It is the Examiner's position that this limitation is not supported in the original disclosure and is the exact opposite from what applicant was originally claiming. The Examiner notes original claim 19, now canceled.

19. The prosthetic device of claim 1, wherein the augment material is adapted to be substantially absorbed by a patient's body after implantation and to be substantially replaced by scar tissue.

It is the Examiner belief that all materials listed in claim 5 which depend from claim 1 meet the limitation of claim 19 and would be substantially replaced by scar tissue. There is no taught formulation as claimed. As far as the rejection as being obvious in view of Kluber, it is the Examiner’s position that it would have been obvious to one having ordinary skill in the art, and a step backward from the inventive teachings of Kluber, to have made the augment out of any material which is not bioresorbable, and therefore, would not be substantially replaced by scar tissue. Acetabular liner components are **well known** in the art being formed from non-bioresorbable materials such as polyethylene. The rejection reads:

“It would have been obvious to one having ordinary skill in the art to have utilized any of the known biologic materials (bioresorbable or non-bioresorbable)… Kuber teaches the semiannular augment being formed of PLLA. It is well know in the art to form femoral head

retaining structures from other materials including non-resorbable material. It would have been obvious to one having ordinary skill in the art to have made/tried the augment of Kuber comprising any known material in the prosthetic art having predictable results."

Therefore, the claim limitation wherein the augment material is formulated not to transform into scar tissue has been met by the rejection.

Additionally, applicant argued under the anticipated portion of the rejection (now withdrawn) but not in the obvious portion of the rejection that the augment of Kuber is not supplemented with at least one of an agent to promote the formation of scar tissue as required by claim 1. This is only a partial quotation of the limitation. The limitation reads in full, *"wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent*". Therefore, claim 1 only requires one of the three to fulfill the claim language. As stated in the rejection:

"It would have been obvious to one having ordinary skill in the art to have utilized any of the known biologic materials *(bioresorbable or non-bioresorbable) or combinations thereof and to include an agent to promote scar tissue, clotting, and antibacterial agent for their known biocompatibility and characteristic such as preventing a bacterial infection." And, " It would have been obvious to one having ordinary skill in the art to have made/tried the augment of Kuber comprising any known material in the prosthetic art having predictable results."*

It is the Examiner's strong position that applicant claiming an antibacterial agent, for example, on a bone prosthesis to prevent infection is not a novel, patentable limitation. Similar for a clotting agent or even an agent to promote the formation of scar tissue. Therefore, the limitation has been met by the rejection.

Group 2: Claims 27-32 and 37.

Applicant argues that Kluber fails to teach one integrated fastener. The Examiner believes this was clearly addressed in the rejection as follows:

"Regarding claims 2 and 29, see fastener C made of PLLA.

Regarding claims 4 and 30, fastener C is a screw.

*Regarding **at least claim 14**, the screw is integrated.*

Regarding at least claim 15, applicant's specification teaches various fastening means including screws; see paragraph 0032 and 4. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to snap-on retention members. Applicant has not disclosed that said configuration provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either screws or a snap-on configuration. Therefore, it would have been obvious to one of ordinary skill in the art to modify Kuber to obtain the invention as claimed with expected results."

The Examiner places emphasis on the underlined portion; the screw is clearly an integrated fastener and was addressed.

Applicant further argues that claim 27 requires an augment material "formulated not to transform into scar tissue". As stated above, it is the Examiner's position that it would have been obvious to one having ordinary skill in the art, and a step backward from the inventive teachings of Kluber, to have made the augment out of any material which is not bioresorbable, and therefore, would not be substantially replaced by scar tissue. The rejection reads:

"It would have been obvious to one having ordinary skill in the art to have utilized any of the known biologic materials (bioresorbable or non-bioresorbable)… Kuber teaches the semiannular augment being formed of PLLA. It is well know in the art to form femoral head retaining structures [including the augments] from other materials including non-resorbable material. It would have been obvious to one having ordinary skill in the art to have made/tried the augment of Kuber comprising any known material in the prosthetic art having predictable results."

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Bruce E Snow/

Primary Examiner, Art Unit 3738

Conferees:

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738

/Thomas Barrett/

TQAS TC3700